

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SURGIQUEST, INC.,)	
)	
Plaintiff,)	
)	C.A. No. 14-382-GMS
v.)	
)	JURY TRIAL DEMANDED
LEXION MEDICAL, LLC,)	
)	
Defendant.)	

**LEXION MEDICAL, LLC’S FIRST AMENDED ANSWER,
AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO
PLAINTIFF’S SUPPLEMENTAL AND AMENDED COMPLAINT**

Defendant Lexion Medical, LLC (“Lexion”) files this Answer to the Supplemental and Amended Complaint (the “Complaint”) filed by Plaintiff SurgiQuest, Inc. (“Plaintiff” or “SurgiQuest”) and alleges as follows:

THE PARTIES

1. Lexion is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 1 of the Complaint, and therefore denies the same.
2. Lexion admits the allegations of paragraph 2 of the Complaint.

JURISDICTION AND VENUE

3. Lexion admits that SurgiQuest asserts jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338 and 1367 and purports to pursue an action for false and/or misleading advertising under the Lanham Act and claims under Delaware state law, as well as a declaratory judgment that SurgiQuest’s conduct does not violate the Lanham Act. Lexion denies that it has engaged in false and/or misleading advertising or any other conduct in violation of the Lanham Act or Delaware state law as alleged in the Complaint. Lexion further denies that SurgiQuest’s conduct does not violate the Lanham Act as it has made false and/or misleading statements in connection with the marketing and sale of the AirSeal system.

Lexion denies any and all remaining allegations set forth in paragraph 3 of the Complaint.

4. Lexion admits the allegations of paragraph 4 of the Complaint.

ALLEGED FACTS

5. Lexion admits that SurgiQuest offers for sale and sells the AirSeal system used in laparoscopic surgery. Lexion denies the remaining allegations in paragraph 5 of the Complaint.
6. Lexion admits the allegations of paragraph 6 of the Complaint.
7. Lexion is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 7 of the Complaint, and therefore denies the same.
8. Lexion admits the allegations of paragraph 8 of the Complaint.
9. Lexion admits that during laparoscopic surgery, the abdominal wall is elevated above the organs with insufflation gas (usually carbon dioxide) to increase working space and visibility. It is unclear what is meant by “occasionally,” “typically,” or “incidents,” and therefore Lexion denies the remaining allegations of paragraph 9 of the Complaint.
10. Lexion denies that its Insuflow® products or system are “traditional systems” insofar as it comprehends that term. Otherwise, it is unclear what is meant by “traditional” or “regularly.” Therefore, Lexion denies the remaining allegations of paragraph 10 of the Complaint.
11. It is unclear what is meant by “such valves” or “older-style” and therefore Lexion denies the allegations in paragraph 11 of the Complaint.
12. Lexion denies the allegations in paragraph 12 of the Complaint.
13. Lexion admits only that SurgiQuest sells a product called the AirSeal system. Except as specifically admitted, Lexion is without knowledge or information sufficient to form a

belief as to the truth or falsity of the allegations in paragraph 13 of the Complaint, and therefore denies the same.

14. Lexion is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 14 of the Complaint, and therefore denies the same.

15. Lexion alleges that Exhibit A speaks for itself and objects to and denies any characterization that is inconsistent with the attached documents. Lexion denies the remaining allegations in paragraph 15 of the Complaint.

16. Lexion is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 16 of the Complaint, and therefore denies the same.

17. Lexion is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 17 of the Complaint, and therefore denies the same.

18. Lexion admits only that insufflation gas should be warmed and humidified to reduce certain side effects from the introduction to the peritoneal cavity of cold, dry gas. Except as specifically admitted, Lexion is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 18 of the Complaint, and therefore denies the same.

19. Lexion is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 19 of the Complaint, and therefore denies the same.

20. Lexion admits only that it markets products to surgeons, nurses, and hospitals throughout the United States, including Delaware. Except as otherwise admitted, Lexion is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations in paragraph 20 of the Complaint, and therefore, denies the same.

21. Lexion admits only that Exhibit B purports to be copies of adverse event reports. Except as admitted, Lexion is without knowledge or information sufficient to form a belief as to the truth or falsity of the information contained in the purported reports attached to Exhibit B and denies the remaining allegations in paragraph 21 of the Complaint.
22. Lexion admits the allegations in paragraph 22 of the Complaint.
23. Lexion admits that as part of the Minnesota lawsuit it claimed that SurgiQuest had engaged in false advertising. Except as specifically admitted, Lexion denies the allegations in paragraph 23 of the Complaint.
24. Lexion admits the allegations set forth in paragraph 24 of the Complaint.
25. Lexion admits the allegations set forth in paragraph 25 of the Complaint.
26. Lexion is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 26 of the Complaint, and therefore denies the same.
27. Lexion is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 27 of the Complaint, and therefore, denies the same.
28. Lexion denies that Plaintiff's conduct in marketing, providing and selling the AirSeal system does not violate the Lanham Act. Lexion is otherwise without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations in paragraph 28 of the Complaint, and therefore denies the same.

Lexion Has Not Engaged In False and Misleading Advertising

29. Lexion admits only that it markets some of its devices based upon heating and humidifying insufflation gas to 95° F and 95% relative humidity to reduce certain side effects of laparoscopic surgery. Except as specifically admitted, Lexion denies the remaining allegations in paragraph 29 of the Complaint.
30. Lexion admits that its Chief Medical Officer is Dr. Douglas E. Ott and that research on heating and humidifying insufflation gas was conducted by him. Except as specifically admitted, Lexion denies the remaining allegations in paragraph 30 of the Complaint.
31. Lexion objects to and refutes the characterization of a conviction of Dr. Ott that is more than twenty (20) years old, is irrelevant, prejudicial and should have no bearing in this matter. Lexion alleges that Dr. Ott entered a plea of not guilty as to a scheme to defraud the Kentucky Medicaid Program and to filing fraudulent Medicaid Claims. Lexion further alleges that Dr. Ott was tried before a jury and testified during the trial. The jury never found him guilty, and the trial resulted in a hung jury. Lexion admits only that after expending substantial resources on the first trial that did not result in conviction, Dr. Ott withdrew his plea of not guilty and entered a guilty plea on October 11, 1982 rather than endure a second trial.
32. Lexion denies the remaining allegations set forth in paragraph 32 of the Complaint.
33. Lexion admits only that Dr. Ott's paper, Reduction of Laparoscopic-Induced Hypothermia, Postoperative Pain and Recovery Room Length of Stay By Pre-Conditioning Gas With The Insuflow® Device: A Prospective Randomized Controlled Multi-Center Study (1999), was published in the Journal of the Society of Laparoendoscopic Surgeons and that Dr. Ott sits on the editorial review board of that

Journal. Except as specifically admitted, Lexion denies the remaining allegations in paragraph 33 of the Complaint.

34. It is unclear what is meant by “study,” “little,” or “unverifiable,” and therefore Lexion denies the allegations in paragraph 34 of the Complaint.

35. Lexion is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 35 of the Complaint, and therefore, denies the same.

36. Lexion alleges that the article by Nguyen identified in paragraph 36 of the Complaint speaks for itself. Lexion is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations in paragraph 36 of the Complaint, and denies the same.

37. Lexion alleges that the article by Farley identified in paragraph 37 speaks for itself. Lexion is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations set forth in paragraph 37 of the Complaint, and denies the same.

38. Lexion alleges that the article by Champion identified in paragraph 38 of the Complaint speaks for itself. Lexion is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations set forth in paragraph 38 of the Complaint, and denies the same.

39. Lexion alleges that the article by Neudecker identified in paragraph 39 speaks for itself. Lexion denies any remaining allegations in paragraph 39 of the Complaint.

40. Lexion alleges that the article by Davis identified in paragraph 40 of the Complaint speaks for itself. Lexion denies any remaining allegations in paragraph 40 of the Complaint.
41. Lexion denies the allegations in paragraph 41 of the Complaint.
42. Lexion denies the allegations in paragraph 42 of the Complaint.
43. Lexion alleges that the articles cited in paragraph 43 of the complaint and Lexion's summary of the same on Lexion's website speak for themselves. Lexion denies the remaining allegations set forth in paragraph 43 of the Complaint.
44. Lexion denies the allegations set forth in paragraph 44 of the Complaint.
45. Lexion admits that the memorandum was signed by its Chief Executive Officer, Patrick Spearman. Lexion further admits that the memorandum was sent to certain customers and or prospective customers of SurgiQuest. Lexion denies the remaining allegations in paragraph 45 of the Complaint.
46. Lexion denies the allegations set forth in paragraph 46 of the Complaint.
47. Lexion is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in paragraph 47 of the Complaint, and therefore denies the same.
48. Lexion denies the allegations set forth in paragraph 48 of the Complaint.
49. Lexion denies the allegations set forth in paragraph 49 of the Complaint.
50. Lexion denies the allegations set forth in paragraph 50 of the Complaint.
51. Lexion denies the allegations set forth in paragraph 51 of the Complaint.

COUNT I

Violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)

52. In response to paragraph 52 of the Complaint, Lexion repeats and realleges, as if fully set forth herein, its answers, responses and objections to the allegations in paragraphs 1 through 51 of the Complaint.
53. Lexion denies the allegations set forth in paragraph 53 of the Complaint.
54. Lexion admits that in paragraph 54, the Complaint asserts certain statutory language from Section 1125(a)(1)(A) and (B) of the Lanham Act. Except as expressly admitted, Lexion denies that it has violated the Lanham Act and denies any remaining allegations in paragraph 54 of the Complaint.
55. Lexion denies the allegations set forth in paragraph 55 of the Complaint.
56. Lexion denies the allegations set forth in paragraph 56 of the Complaint.
57. Lexion denies the allegations set forth in paragraph 57 of the Complaint.
58. Lexion denies the allegations set forth in paragraph 58 of the Complaint.
59. Lexion denies the allegations set forth in paragraph 59 of the Complaint.
60. Lexion denies the allegations set forth in paragraph 60 of the Complaint.
61. Lexion denies the allegations set forth in paragraph 61 of the Complaint.
62. Lexion denies the allegations set forth in paragraph 62 of the Complaint.

COUNT II

Declaratory Judgment

63. In response to paragraph 63 of the Complaint, Lexion repeats and realleges, as if fully set forth herein, its answers, responses and objections to the allegations in paragraphs 1 through 62 of the Complaint.

64. Lexion admits only that the Complaint purports to assert a claim for Declaratory Judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. Except as specifically admitted, Lexion denies the remaining allegations set forth in paragraph 64 of the Complaint.
65. Lexion admits only that an actual and justiciable controversy exists between Lexion and SurgiQuest with respect to the matters set forth herein. Except as specifically admitted, Lexion denies the remaining allegations set forth in paragraph 65 of the Complaint.
66. Lexion denies the allegations set forth in paragraph 66 of the Complaint.
67. Lexion denies the allegations set forth in paragraph 67 of the Complaint.
68. Lexion denies the allegations set forth in paragraph 68 of the Complaint.

COUNT III
Delaware Deceptive Trade Practices Act
DEL. CODE ANN. TIT. 6 § 2531 et. seq.

69. In response to paragraph 69 of the Complaint, Lexion repeats and realleges, as if fully set forth herein, its answers, responses and objections to the allegations in paragraphs 1 through 68.
70. Lexion denies the allegations set forth in paragraph 70 of the Complaint.
71. Lexion denies the allegations set forth in paragraph 71 of the Complaint.
72. Lexion denies the allegations set forth in paragraph 72 of the Complaint.
73. Lexion denies the allegations set forth in paragraph 73 of the Complaint.
74. Lexion denies the allegations set forth in paragraph 74 of the Complaint.
75. Lexion denies the allegations set forth in paragraph 75 of the Complaint.
76. Lexion denies the allegations set forth in paragraph 76 of the Complaint.
77. Lexion denies the allegations set forth in paragraph 77 of the Complaint.

COUNT IV
Common Law Unfair Competition

78. In response to paragraph 78 of the Complaint, Lexion repeats and realleges, as if fully set forth herein, its answers, responses and objections to the allegations in paragraphs 1 through 77 of the Complaint.

79. Lexion denies the allegations set forth in paragraph 79 of the Complaint.

80. Lexion denies the allegations set forth in paragraph 80 of the Complaint.

81. Lexion denies the allegations set forth in paragraph 81 of the Complaint.

82. Lexion denies the allegations set forth in paragraph 82 of the Complaint.

83. Lexion denies the allegations set forth in paragraph 83 of the Complaint.

84. Lexion denies the allegations set forth in paragraph 84 of the Complaint.

GENERAL DENIAL

Lexion denies that SurgiQuest is entitled to any of the relief requested in its Complaint, including the relief requested in sub-paragraphs 1-10 on pages 16 through 18 of the Complaint, or to any relief in any form whatsoever from Lexion. SurgiQuest's request for relief should, therefore, be denied in its entirety and the Complaint dismissed with prejudice. Lexion further denies each and every allegation in the Complaint to which it has not specifically responded.

SURGIQUEST'S DEMAND FOR JURY TRIAL

Lexion admits that SurgiQuest has requested a trial by jury.

DEFENSES

Lexion asserts and alleges the following defenses in response to the allegations in the Complaint, undertaking the burden of proof only as to those defenses deemed affirmative defenses by law, regardless of how such defenses are denominated herein:

FIRST DEFENSE

SurgiQuest's purported claims, and each of them, are barred in whole or in part by one or more equitable doctrines including at least laches, acquiescence, unclean hands, and estoppel.

SECOND DEFENSE

Any and all acts alleged to have been committed by Lexion, if performed, were performed with lack of knowledge and lack of willful intent.

THIRD DEFENSE

SurgiQuest's causes of action, and each of them, are barred to the extent SurgiQuest is seeking double recovery for the same alleged wrongs.

RESERVATION OF ADDITIONAL DEFENSES & CLAIMS

Lexion is currently without sufficient knowledge or information upon which to form a belief as to whether additional defenses or counterclaims are available. Therefore, Lexion reserves the right to amend this Answer to assert any such additional defenses or counterclaims based on legal theories that may become apparent through discovery or through further legal analysis of Plaintiff's positions, claims and allegations in this litigation.

LEXION'S COUNTERCLAIMS

For its counterclaims against Plaintiff (SurgiQuest), defendant and counterclaimant Lexion alleges as follows:

1. The counterclaims include claims that SurgiQuest: has engaged in false and/or misleading advertising in violation of § 43(a) of the Lanham Act, (b) has made false and/or misleading statements or advertisements that violate the Delaware Deceptive Trade Practices Act or the common law of Delaware, and (c) has made false and/or

misleading statements that constitute unfair competition under the common law of Delaware.

NATURE OF THE COUNTERCLAIM

2. This is an action for false and/or misleading representations or descriptions of facts, false advertising, unfair competition, and related claims under the United States Trademark (Lanham) Act, 15 U.S.C. §§ 1051 *et seq.* (as amended), and Delaware statutory and common law.
3. This action arises from SurgiQuest's intentional false and/or misleading representations of fact concerning the nature, quality and/or characteristics of its products. More specifically, SurgiQuest has represented on its website on the Internet, in other electronic and printed materials and orally to customers that its AirSeal system for laparoscopic and robotic surgery avoids the need for carbon dioxide heater/humidifiers. SurgiQuest has also represented that the AirSeal product provides reduced shoulder pain when compared to conventional systems. As another example, SurgiQuest has made various claims in its advertising concerning the ability of the AirSeal to evacuate smoke. For example, SurgiQuest advertises that its AirSeal System allows for "smokeless laparoscopy" and provides a "smoke free working environment." Further, SurgiQuest represents that the AirSeal device "evacuates and filters smoke to protect [the] patient and surgical team." SurgiQuest also makes various claims in its advertising regarding the capabilities of the AirSeal insufflator. For example, SurgiQuest advertises that the AirSeal is a "carbon dioxide insufflator" that includes an "air barrier" that is "airtight" In addition, SurgiQuest refers to the product as an "AirSeal" when no "air seal" is created. A further example of SurgiQuest's representations include that the AirSeal is safe and "achieves a

level of safety and efficiency that had never been available to surgeons before.”

SurgiQuest also represents, for example, that doctors are endorsing the AirSeal device using the phrase “[t]heir words . . . not ours” in its advertisements.

4. SurgiQuest’s actions and/or statements constitute false and/or misleading representations or descriptions of facts, false advertising, and/or unfair competition. Indeed, SurgiQuest’s false and/or misleading statements appeared in commercial advertisements, marketing and promotional materials relating to its own products or those of Lexion.

These statements actually deceived or have the tendency to deceive a substantial segment of purchasers or prospective purchasers of medical devices. Further, SurgiQuest’s false and/or misleading statements are material in that they are likely to, and in fact did, influence the purchasing decisions relating to the relevant medical products at issue.

SurgiQuest also caused its false and/or misleading statements to enter or affect interstate commerce.

5. On information and belief, SurgiQuest’s false and/or misleading representations of fact have, are likely to and will inevitably cause injury and harm to Lexion by, in part, demeaning, disparaging, lessening and/or tarnishing the goodwill and business reputation enjoyed by Lexion, harm Lexion’s credibility in the trade and reduce the demand for Lexion’s products and/or diverting sales from Lexion to SurgiQuest.
6. Lexion has taken steps to avoid the need for court intervention by providing notice of SurgiQuest’s wrongdoing and requesting that it cease and desist from its false and/or misleading representations. While SurgiQuest initially agreed to remove certain representations from its website, it thereafter disseminated further similar false and/or misleading representations of fact. Notwithstanding Lexion’s written demand and prior

complaint that SurgiQuest cease and desist from such unlawful conduct, SurgiQuest continues to willfully and intentionally engage in false and/or misleading representations or descriptions of fact, false advertising and unfair competition.

7. SurgiQuest's unlawful actions are damaging to Lexion and it is clear that SurgiQuest will not stop its wrongdoing unless and until ordered to do so by this Court. As a result, Lexion seeks a permanent injunction, the recovery of any actual damages, treble damages, profits, costs, attorneys' fees, punitive damages, and other relief as more fully set forth below.

THE PARTIES

8. Counterclaimant, Lexion is a Delaware corporation with a principal place of business at 545 Atwater Circle, St. Paul, MN 55103.
9. Counter-defendant, SurgiQuest, on information and belief, is Delaware corporation with its principal place of business at 333 Quarry Road, Milford, CT 06460.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1331, 28 U.S.C. § 1338(a), and 15 U.S.C. § 1121 because this action arises under the Lanham Act, 15 U.S.C. § 1051. The Court has supplemental jurisdiction over the claims arising out of state law pursuant to 28 U.S.C. §§ 1338(b) and 1367.
11. The Court has personal jurisdiction over SurgiQuest by virtue of SurgiQuest's filing of the Complaint against Lexion in this Court.
12. Venue in this district is proper pursuant to 28 U.S.C. § 1391(b) and (c).

FACTS COMMON TO ALL COMMON TO ALL CLAIMS FOR RELIEF

13. Lexion is a medical device company engaged in the design and manufacture of advanced technologies for surgical procedures. Lexion is committed to promoting superior healthcare by providing cost-effective technologies that help patients return to their normal, productive lives faster.
14. As one product in its line, Lexion sells, offers for sale, and manufactures the Insuflow® insufflation gas treatment apparatus used in laparoscopic surgery.
15. The Insuflow® apparatus humidifies and warms the carbon dioxide gas to 95°F and 95% humidity used for insufflation in laparoscopic surgery.
16. The Insuflow® system and method for conditioning insufflation gas has been scientifically proven to reduce the side effects linked to the use of unconditioned insufflation gas, such as post-operative shoulder and abdominal pain, hypothermia, and inflammatory response to surgery. Others had previously tried and failed to address the long-felt need for a solution to at least some of these problems.
17. After extensive experimentation, Dr. Douglas E. Ott and his fellow inventors invented a method to reduce the incidence and effect of the aforementioned post-operative problems. The Insuflow® device has been shown to result in less post-operative pain, reduced hypothermia, improved outcomes, faster and improved recovery times, and improved visualization.
18. Lexion's Chief Medical Officer, Dr. Ott, lead the research regarding heating and humidifying carbon dioxide used for insufflation and led the development of the Insuflow® device.
19. In September 1999, The American Association of Gynecologic Laparoscopists informed Dr. Ott that he had been awarded first prize for the Daniel F. Kott Best New

Instrumentation competition for the Insuflow® device, and the award would be presented in November 1999 during the Honorary Luncheon at the Global Congress of Gynecologic Endoscopy, AAGL 28th Annual Meeting.

20. Lexion markets its Insuflow® device to surgeons, nurses, and hospitals throughout the United States.
21. Upon information and belief, SurgiQuest is engaged in the design and manufacture of surgical devices and technologies, including devices used in laparoscopic surgery.
22. Upon information and belief, SurgiQuest markets an access port or valve-free trocar under the brand AirSeal, which can be used in conjunction with its iFS (Intelligent Flow System).
23. Upon information and belief, SurgiQuest's AirSeal device, by itself or used in conjunction with the iFS system, is incapable of sufficiently warming or humidifying the insufflation gas.
24. Upon information and belief, SurgiQuest markets its AirSeal device to surgeons, nurses, and hospital administrators throughout the United States.
25. Upon information and belief, SurgiQuest has represented in advertisements, marketing collateral, and oral statements disseminated and spoken to surgeons, nurses, and hospital administrators throughout the United States that use of its AirSeal device permits discontinuance of the use of carbon dioxide warmers and humidifiers, like the Insuflow® apparatus, during laparoscopic procedures.
26. The July 2013 issue of Outpatient Surgery Magazine Online discusses the AirSeal iFS laparoscopic access system from SurgiQuest. The magazine states that the AirSeal system "obviates the need for smoke evacuation devices, CO₂ warmers and devices to

prevent loss of pneumoperitoneum.” Upon information and belief, the magazine received this information regarding the AirSeal system obviating the need for smoke evacuation devices and CO₂ warmers from a SurgiQuest representative. Upon information and belief, in July 2013 a representative of SurgiQuest distributed a “Sample Cost Comparison” to ABC Medical Center comparing the cost of ABC Medical Center’s current product utilization to the cost of the AirSeal device. For Robotic Prostatectomy and Robotic Hysterectomy, the sample cost comparison lists that a “smoke evacuator” and “CO₂ Warmer/Humidifier” are “Not Needed.” Upon information and belief, SurgiQuest’s statements that carbon dioxide warmers and humidifiers are not needed when the SurgiQuest AirSeal system is used, is intended to convey and in fact conveys the false and/or misleading message that the SurgiQuest device itself reduces the side effects linked to the use of unconditioned gas, such as reducing post-operative shoulder pain, hypothermia, and recovery time without the use of carbon dioxide warmers and humidifiers.

27. Upon information and belief, SurgiQuest’s AirSeal device does not heat, warm, or humidify carbon dioxide used for insufflation sufficiently to provide the benefits realized from the use of heated and humidified carbon dioxide. SurgiQuest’s representations that a carbon dioxide warmer and humidifier is not needed are false and/or misleading.
28. Upon information and belief, there are no published medical journal articles to substantiate SurgiQuest’s false and/or misleading representations.
29. Upon information and belief, Lexion has lost sales to prospective and current customers throughout the United States because of SurgiQuest’s false and/or misleading

advertisements, marketing collateral, and oral misrepresentations, including, but not limited to:

- a. Texas Health Harris Methodist Hospital Southwest, Fort Worth, TX;
- b. Medical City Hospital, Dallas, TX;
- c. University Texas Southwestern (Saint Paul University Hospital), Dallas, TX;
- d. The Women's Hospital of Texas, Houston, TX;
- e. Houston Methodist Hospital, Houston, TX; and
- f. Memorial Hermann Southwest Hospital, Houston, TX.

30. Upon information and belief, Lexion has been injured as a result of SurgiQuest's false and/or misleading advertisements, marketing efforts or collateral, and/or oral representations about its AirSeal device by the loss of sales of Lexion's Insuflo[®] device.

31. On information and belief, SurgiQuest's false and/or misleading representations of fact are likely to, have and will inevitably harm and diminish Lexion's goodwill, business reputation and credibility in the trade, and the demand for Lexion's products.

32. In a letter dated October 8, 2012, Lexion protested and objected to SurgiQuest's representations of fact concerning its AirSeal device. SurgiQuest agreed to remove certain material from its web site. Notwithstanding its representations, SurgiQuest continued its aforementioned false and/or misleading representations and such false and/or misleading representations were made in bad faith with an intent to confuse the relevant consumers and with an intent to bolster sales of SurgiQuest's products at the expense of Lexion's products.

33. Further, at this time, SurgiQuest never once objected to Lexion's advertising or marketing of its Insuflow® apparatus or alleged that Lexion engaged in any acts of unfair competition or false and/or misleading advertising.
34. Yet, on March 26, 2014, SurgiQuest filed its Complaint naming Lexion as a defendant and alleged that Lexion made false and/or misleading advertisements and oral statements constituting false and/or misleading advertising in violation of § 43 of the Lanham Act, the Delaware Deceptive Trade Practices Act, and common law unfair competition.
35. On information and belief, SurgiQuest's AirSeal insufflator sucks air into the abdomen when used in AirSeal mode. For example, the AirSeal may suck air into the abdomen when there is a leak, which allows insufflation gas to escape from the abdomen. As another example, the AirSeal may suck air into the abdomen when suction is used during a surgery that removes insufflation gas from the abdomen. This can alter the concentration of carbon dioxide gas to other gasses inside the abdomen. According to a SurgiQuest Patent, altering the concentration of carbon dioxide gas to other gasses in a body cavity is "typically undesirable for the safety of the patient." Upon information and belief, one potential risk from sucking air into the abdomen is a potentially fatal air embolism. Upon information and belief, SurgiQuest was on notice of this risk and continued its false and/or misleading advertising anyway. Various SurgiQuest advertising claims are false and/or misleading given the operation of the AirSeal system. As an example, SurgiQuest advertises that the AirSeal is a "carbon dioxide insufflator" that includes an "air barrier" that is "airtight." In addition, SurgiQuest refers to the product as an "AirSeal" when no "airseal" is created. Air can be sucked in through the alleged "airseal." A further example of SurgiQuest's representations include that the

AirSeal is safe and “achieves a level of safety and efficiency that had never been available to surgeons before.” But in fact, sucking air into the abdomen is “typically undesirable for the safety of the patient” as SurgiQuest claims.

36. On information and belief, the SurgiQuest AirSeal system causes surgical smoke to escape from the Airseal trocar. On information and belief, the SurgiQuest AirSeal system does not remove toxic and/or carcinogenic gasses from surgical smoke. Instead, these gasses are released into the operating room and/or recirculated to the patient. On information and belief, SurgiQuest was aware of these facts and continued to make false and/or misleading statements anyway. Various SurgiQuest advertising claims are false and/or misleading given the operation of the AirSeal system. As an example, SurgiQuest advertises that the AirSeal system includes an “air barrier” that is “airtight.” In addition, SurgiQuest refers to the product as an “Airseal” when no “airseal” is created. Smoke can escape through the alleged “airseal.” A further example of SurgiQuest’s representations include that the AirSeal is safe and “achieves a level of safety and efficiency that had never been available to surgeons before.” Given the release of surgical smoke into the operating room and the failure to remove toxic and/or carcinogenic gasses from the smoke, this statement is false. Additional statements related to smoke evacuation are false as well. For example, SurgiQuest advertises that its AirSeal System allows for “smokeless laparoscopy” and provides a “smoke free working environment.” Further, SurgiQuest represents that the AirSeal device “evacuates and filters smoke to protect the patient and surgical team.” Because each of these issues impacts the health and safety of the patient and/or the operating room staff, each is material and likely to influence

purchasing decisions. Upon information and belief, there has been actual deception as well as a tendency to deceive a substantial portion of the intended audience.

37. An actual and justiciable case or controversy has arisen and presently exists between SurgiQuest on one hand and Lexion on the other to which Lexion desires a declaration of rights pursuant to 28 U.S.C. § 2201(a) and Rule 57 of the Federal Rules of Civil Procedure.

COUNTERCLAIM - COUNT I

(Federal False Advertising)
(Lanham Act § 43(a), 15 U.S.C. § 1125(a))

38. Lexion restates and reincorporates by reference each and every allegations in paragraphs 1-37 as if fully set forth herein.
39. Upon information and belief, SurgiQuest has made false and/or misleading statements of fact about its AirSeal device in its advertisements, marketing collateral, and oral statements.
40. Upon information and belief, SurgiQuest's false and/or misleading statements of fact have actually deceived or tended to deceive a substantial segment of the relevant consumers for devices used during laparoscopic surgery.
41. Upon information and belief, SurgiQuest's false and/or misleading statements of fact are material and have influenced the buying decisions of consumers for laparoscopic surgery devices throughout the United States.
42. SurgiQuest's aforementioned activities constitute unfair competition and false and/or misleading descriptions or representations of fact, which are likely to cause confusion or mistake, or to deceive the relevant consumers or the relevant public in and affecting interstate commerce, all in violation of Section 43(a)(1)(A) of the Lanham Act, 15 U.S.C. §1125(a)(1)(A).
43. SurgiQuest's acts were and are intentionally designed to entice the relevant customer to purchase its products or services at the expense of Lexion's products.
44. Upon information and belief, the relevant consumers are likely to be confused, deceived and misled by SurgiQuest's false and/or misleading statements and representations, and have purchased or are likely to purchase products and services from SurgiQuest as a

result thereof.

45. SurgiQuest acted willfully and deliberately after being placed on notice by Lexion of its wrongdoing, with the intent to unfairly commercially benefit at Lexion's expense.

46. As a direct and proximate result of the acts of SurgiQuest as alleged herein, Lexion has suffered and will continue to suffer great damage to its business, goodwill, reputation, and profits, while SurgiQuest is profiting at Lexion's expense.

47. Lexion has no adequate remedy at law for this unfair competition and false advertising. Unless SurgiQuest is permanently enjoined by the Court, Lexion will continue to suffer irreparable harm.

48. SurgiQuest has profited from its unlawful actions and has been unjustly enriched to the detriment of Lexion. SurgiQuest's unlawful actions have caused Lexion monetary damage in an amount presently unknown, but in an amount to be determined at trial.

COUNTERCLAIM - COUNT II

(Delaware Deceptive Trade Practices Act)
(Del. Code Ann., tit. 6, §2531 et seq. (1953))

49. Lexion restates and reincorporates by reference each and every allegation in paragraphs 1-48 as if fully set forth herein.

50. SurgiQuest has made false and/or misleading statements in its advertisements and marketing collateral and has made false and/or misleading oral statements to customers and prospective customers, including surgeons, nurses, and/or hospital administrators throughout the United States.

51. SurgiQuest's false and/or misleading statements in its advertisements, marketing collateral, and its false and/or misleading oral statements disparages the Lexion

Insuflow® device and violate the Delaware Deceptive Trade Practices Act and the common law of Delaware.

52. Unless this Court enjoins SurgiQuest from continuing to make these false and/or misleading statements, the false and/or misleading advertising will continue to cause Lexion to suffer a loss of sales, profits, and goodwill, which will irreparably harm Lexion.

53. SurgiQuest's false and/or misleading statements are willful, with malicious and deceptive intent, making this an exceptional case.

54. Lexion has no adequate remedy at law.

COUNTERCLAIM - COUNT III
(Common Law Unfair Competition)

55. Lexion restates and reincorporates by reference the allegations in paragraphs 1-54 as if fully set forth herein.

56. Upon information and belief, SurgiQuest has made false and/or misleading statements of fact about its AirSeal device in its advertisements, marketing collateral, and oral statements to customers and prospective customers, including, surgeons, nurses, and hospital administrators throughout the United States.

57. SurgiQuest's unlawful acts, as described above, constitute unfair competition under Delaware law.

58. Upon information and belief, consumers of laparoscopic surgery devices would have bought Lexion's Insuflow® device instead of SurgiQuest's AirSeal device, but for SurgiQuest's unfair competition.

59. SurgiQuest's unlawful actions have caused, and will continue to cause, Lexion irreparable harm unless enjoined.

60. SurgiQuest has profited from its unlawful actions and has been unjustly enriched to the detriment of Lexion. SurgiQuest's unlawful actions have caused Lexion monetary damage in an amount presently unknown, but in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Lexion prays for the following relief:

- A. Dismiss the SurgiQuest Complaint with prejudice;
- B. That judgment be entered in favor of Lexion and against SurgiQuest on each and every count of the Complaint and on each and every count of its Counterclaim;
- C. Enter a judgment that Lexion has not made any false and/or misleading statements that constitute false advertising in violation of the Lanham Act, the Delaware Deceptive Trade Practices Act, or common law unfair competition;
- D. That SurgiQuest and SurgiQuest's agents, servants, attorneys, employees, any companies owned or controlled by SurgiQuest, and its affiliates, successors and assigns, and all of those in active concert or participation with any of them who receive notice directly or otherwise, be permanently enjoined and restrained from:
 - a. Unfairly competing with Lexion in any matter whatsoever;
 - b. Making false and/or misleading statements in its advertisements, marketing material, or oral statements that the AirSeal and any related products are capable of reducing the side effects linked to the use of unconditioned insufflation gas;
 - c. Making false and/or misleading statements in its advertisements, marketing material, or oral statements that it is unnecessary to warm and humidify the insufflation gas to reduce the side effects linked to the use of unconditioned insufflation gas; and

- d. Engaging in any deceptive trade practice or false advertising with respect to Lexion or Lexion's Insuflo® device.
- E. Ordering that SurgiQuest file with the Court and serve upon Lexion's counsel within thirty days after entry of judgment a report in writing under oath setting forth in detail the manner and form in which SurgiQuest has complied with the requirements of the foregoing injunction and orders including destruction of unauthorized goods under 15 U.S.C. § 1118.
- F. Requiring SurgiQuest to account for and pay over to Lexion the amount of Lexion's damages and the amount of SurgiQuest's profits pursuant to 15 U.S.C. § 1117;
- G. Trebling any damage award pursuant to 15 U.S.C. § 1117;
- H. Find this case exceptional and award Lexion its costs and expenses, including reasonable attorneys' fees, in accordance with the provisions of 15 U.S.C. § 1117;
- I. Requiring SurgiQuest to account for and pay to Lexion the amount of Lexion's damages and SurgiQuest's profits, together with costs and disbursements, including costs of investigation and reasonable attorneys' fees pursuant to title six section 2533 of the Delaware Code;
- J. That Lexion be awarded exemplary and punitive damages under Delaware law for SurgiQuest's willful, intentional and tortious acts.
- K. Award Lexion any other relief, in law and in equity, to which the Court finds Lexion is justly entitled.

DEMAND FOR JURY TRIAL

Lexion demands a trial by jury of all issues so triable in this action.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

OF COUNSEL:

David G. Wille
Paul J. Reilly
Megan LaDriere
BAKER BOTTS LLP
2001 Ross Avenue
Dallas, TX 75201-2980
Tel: (214) 953-6500

Dated: May 9, 2016
1223355 / 41466

By: /s/ Michael B. Rush

David E. Moore (#3983)
Michael B. Rush (#5061)
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
Tel: (302) 984-6000
dmoore@potteranderson.com
mrush@potteranderson.com

Attorneys for Defendant Lexion Medical, LLC